

## REMARKS

The Final Office Action of January 19, 2010 and the Advisory Action of April 8, 2010, have been received and reviewed. In conjunction with the Request for Continued Examination filed herewith, please amend the claims as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration of the claims as amended is requested.

### **The Rejections under 35 U.S.C. § 103(a) are Overcome**

Claims 1-19 and 21-26 stand rejected under 35 U.S.C. 103(a) as assertedly obvious over Krone in view of Lewis and in further view of Suzuki *et al.* (U.S. 6,015,789) (hereinafter “Suzuki”) and Remington’s Pharmaceutical Sciences 1990 18<sup>th</sup> ed., ch. 89 (hereinafter “RPS”) (collectively hereinafter “the references”). Applicants have amended the claims, and partially in view of those amendments, traverse the rejections as hereinafter set forth.

To establish a *prima facie* case of obviousness, the prior art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. Additionally, the Examiner must determine whether there is “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Further, rejections on obviousness grounds “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 1741, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). “Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed . . . . To facilitate review, this analysis should be made explicit.” *Id.* Furthermore, to establish a *prima facie* case of obviousness there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742.

The references cannot render obvious amended claims 1, 14, 24, and 26, as neither the references themselves nor the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention taught or suggested a polytartrate composition having “an initial burst, a lag phase, and thereafter a second burst” in the release of a pharmaceutical composition as recited by claims 1, 14, 24, and 26 or actually “determining a time length of the lag phase” as further required by claim 14.

The Office asserts, at page 3 of the Final Office Action of January 19, 2010, that “Krone et al. teaches that polytartrate preparations have a decreased ‘initial burst’ which implies that they have a second burst.” Applicants disagree. An “initial burst” does not require or imply a second or subsequent burst. The “initial burst,” as would be understood by one of ordinary skill in the art at the time of the invention, refers only to the increased release rate upon initial administration until the preparation settles into its normal release rate.

Krone, at column 1, lines 41-42, teaches that “[a]dditionally, in general after a considerable ‘initial burst’ only a small to moderate release rate is effected.” Thus, Krone agrees with the applicant’s position; to wit: that there can be an “initial burst” followed by a steady state rate without the need for any subsequent burst. As would have been understood by one of ordinary skill in the art at the time of the invention, and as indicated by the cited section of Krone, an “initial burst” simply refers to the immediate increased release of the available pharmaceutical from the composition when it is administered, which is then followed by a more sustained slow or moderate release rate. The Office’s attempt to imply that an “initial burst” must be followed by a subsequent burst is therefore incorrect and does not square with the art cited. Further, nothing in the cited references implies that an “initial burst” must be followed by a second burst.

Moreover, the Office, in the Advisory Action of April 8, 2010, asserts that “the steady state release rate/moderate release, as asserted by the applicant, of the ‘second burst’ of Krone et al. encompasses the ‘second burst’ of the invention.” Applicants disagree. The Office appears to be improperly conflating the term “burst” with the steady state release. As would have been understood by one of ordinary skill in the art at the time of the invention, a “burst” is a release of

pharmaceutical over and above the steady state release. Thus, the steady state release rate/moderate release taught by Krone is not a "burst."

In addition, Krone teaches away from compositions having a substantial "initial burst." For example, column 1, lines 37-42 of Krone teaches the disadvantages of the prior art compositions. One of these disadvantages is the "considerable 'initial burst' followed by only a small to moderate release rate." Further, Krone, at col. 2, lines 21-24, relates that the compositions taught therein display "a strongly decreased 'initial burst' when they were used for depot preparations of pharmaceuticals." Thus, Krone teaches that the "initial burst" is unwanted and thus teaches away from the claimed compositions. Consequently, the applicants submit that the references do not teach or suggest a pulsatile release, including an initial burst, a lag phase, and thereafter a second burst of a pharmaceutically active material. None of the other references overcome the deficiency of Krone.

In addition, applicants submit that the references cannot render obvious claims 2-13, 15-19, 22, 23, and 25, *inter alia*, as each of these claims depends from or otherwise incorporate all of the elements of one of non-obvious amended claims 1, 14, and 24.

In view of at least the foregoing, applicants request withdrawal of the rejections of the claims under 35 U.S.C. § 103(a).

### CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Serial No. 10/501,284

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Daniel J. Morath', with a stylized flourish at the end.

Daniel J. Morath, Ph.D.  
Registration No. 55,896  
Attorney for Applicants  
TRASKBRITT, P.C.  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

Date: May 24, 2010